DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510, 520, and 524

New Animal Drugs; Change of Sponsor

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect a change of sponsor for four new animal drug applications (NADAs) from PM Resources, Inc., to Virbac AH, Inc.

DATES: This rule is effective [*insert date of publication in the* **Federal Register**].

FOR FURTHER INFORMATION CONTACT: David R. Newkirk, Center for Veterinary Medicine (HFV–100), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–6967, e-mail: *davidnewkirk@fda.gov*.

SUPPLEMENTARY INFORMATION: PM Resources, Inc., 13001 St. Charles Rock Rd., Bridgeton, MO 63044, has informed FDA that it has transferred ownership of, and all rights and interest in, the following four approved NADAs to Virbac AH, Inc., 3200 Meacham Blvd., Ft. Worth, TX 76137:

Application No.	21 CFR Section	Trade Name
NADA 007–076	520.2325a	SULFA–NOX (sulfaquinoxaline) Liquid
NADA 008–244	520.2325a	SULFA–NOX (sulfaquinoxaline) Concentrate
NADA 043–215	524.900	PURINA Grub-Kill (famphur)
NADA 092–150	520.2045	PURINA Horse & Colt Wormer (pyrantel tartrate)

Accordingly, the agency is amending the regulations in 21 CFR 520.2045, 520.2325a, and 524.900 to reflect the transfer of ownership.

Following these changes of sponsorship, PM Resources, Inc., is no longer the sponsor of an approved application. Accordingly, § 510.600(c) is being amended to remove the entries for PM Resources, Inc.

This rule does not meet the definition of ''rule'' in 5 U.S.C. 804(3)(A) because it is a rule of ''particular applicability.'' Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

List of Subjects

21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

21 CFR Parts 520 and 524

Animal drugs.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR parts 510, 520, and 524 are amended as follows:

PART 510—NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 510 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

§ 510.600 [Amended]

■ 2. Section 510.600 is amended in the table in paragraph (c)(1) by removing the entry for ''PM Resources, Inc.'' and in the table in paragraph (c)(2) by removing the entry for ''060594''.

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

■ 3. The authority citation for 21 CFR part 520 continues to read as follows:

Authority: 21 U.S.C. 360b.

§ 520.2045 [Amended]

■ 4. Section 520.2045 is amended in paragraph (b)(2) by removing ‘‘060594’’ and by adding in its place ‘‘051311’’.

§ 520.2325a [Amended]

■ 5. Section 520.2325a is amended in paragraph (a)(2) by removing ‘‘060594’’ and by adding in its place ‘‘051311’’.

PART 524—OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS

■ 6. The authority citation for 21 CFR part 524 continues to read as follows:

Authority: 21 U.S.C. 360b.

§ 524.900 [Amended]

■ 7. Section 524.900 is amended in paragraph (c) by removing ‘‘060594’’ and by adding in its place ‘‘051311’’.

Dated: June 18, 2004.

Steven D. Vaughn,

Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

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